IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

INSYS THERAPEUTICS, INC. and INSYS DEVELOPMENT COMPANY, INC.	)	
Plaintiffs,	)	
v.	)	C.A. No._____
ENDO GENERICS HOLDINGS, INC. and PAR PHARMACEUTICAL, INC.	)	
Defendants.	)	

COMPLAINT

Plaintiffs Insys Therapeutics, Inc. ("Insys Tx") and Insys Development Company, Inc. ("Insys Dev") (collectively, "Insys" or "Plaintiffs"), for their Complaint against Defendants Endo Generics Holdings, Inc. ("Endo") and Par Pharmaceutical, Inc. ("Par") (collectively, "Defendants"), hereby allege as follows:

The Parties

1. Insys Tx is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1333 South Spectrum Boulevard, Suite 100, Chandler, Arizona 85286.

2. Insys Dev is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1333 South Spectrum Boulevard, Suite 100, Chandler, Arizona 85286. Insys Dev is a wholly owned subsidiary of Insys Tx.

3. Upon information and belief, Endo is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1400 Atwater Drive, Malvern,

Pennsylvania 19355. Upon information and belief, Endo was formerly named "Par Pharmaceutical Companies, Inc."

4. Upon information and belief, Par is a corporation organized and existing under the laws of New York, having a principal place of business at One Ram Ridge Road, Chestnut Ridge, New York 10977. Upon information and belief, Par is a wholly owned subsidiary of Endo.

Nature of the Action

5. In this action, Plaintiffs seek to oppose Defendants' premature and improper triggering of the litigation process under the Drug Price Competition and Patent Term Restoration Act, as amended (the "Hatch–Waxman Act"), the statute that provides for the resolution of patent disputes over Abbreviated New Drug Applications ("ANDAs") for generic drugs.

6. Receipt of a substantially complete ANDA by the U.S. Food and Drug Administration ("FDA") is a prerequisite that must be satisfied before ANDA applicants like Defendants may lawfully send patent owners like Insys formal notice of an ANDA and any "paragraph IV certification" purportedly contained therein. 21 U.S.C. § 355(j)(2)(B)(ii).

7. Notification of a substantially complete ANDA and paragraph IV certification therein, if valid, begins a statutorily defined time period during which a patent holder like Insys must either sue for patent infringement or risk losing its rights under the Hatch–Waxman Act, which include a statutory 30-month stay during which the FDA cannot approve the ANDA under 21 U.S.C. § 355(j)(5)(B)(iii) and 21 C.F.R. § 314.107(b)(3). Congress designed this 30-month stay in part to allow for the litigation of patent disputes before ANDAs are approved.

8. On information and belief, Defendants submitted to the FDA their ANDA No. 210314 ("the '314 ANDA"), seeking approval of Dronabinol Oral Solution, 5 mg/mL ("the ANDA Product"), which is a generic version of SYNDROS™, Plaintiffs' groundbreaking new product. SYNDROS™ is an innovative treatment for anorexia associated with weight loss in patients with AIDS and for nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.

9. Defendants sent Insys notice of the '314 ANDA, and a purported paragraph IV certification contained therein, in a letter dated June 22, 2017 (collectively, "the Paragraph IV Notification"). The Paragraph IV Notification states that two of Plaintiffs' patents covering SYNDROS™, United States Patent Nos. 8,222,292 ("the '292 patent") and 9,345,771 ("the '771 patent") (collectively, "the patents-in-suit"; Exhibits A–B) are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the generic drug products described in the '314 ANDA.

10. On information and belief, the '314 ANDA was not substantially complete as of June 22, 2017, the date of the Paragraph IV Notification, at least because SYNDROS™ was not commercially available until its launch on July 31, 2017. Indeed, the '314 ANDA must contain proof that the ANDA Product "is bioequivalent to the listed drug" (21 U.S.C. § 355(j)(2)(A)(iv)), which is the reference drug that has previously been approved—i.e., SYNDROS™ (21 U.S.C. §§ 355(j)(2)(A)(i), 355(j)(7)(A)(i)). Yet SYNDROS™ was not commercially available for bioequivalence studies until over five weeks after the date of the Paragraph IV Notification.

11. On information and belief, Defendants therefore lacked proper authority to send, and thus did not lawfully send to Insys, the Paragraph IV Notification. For at least that reason, Defendants' premature attempt to trigger the ANDA patent litigation process contravenes federal

law. This Court should declare the Paragraph IV Notification (and thus Defendants' attempt to trigger the ANDA litigation process) to be improper, null, void, and without legal effect.

12. In the alternative, because the ANDA Product, if approved, will infringe the '292 patent and the '771 patent, Defendants' filing of a related, substantially complete, and otherwise proper ANDA containing a paragraph IV certification and FDA receipt of that filing would constitute infringement under 35 U.S.C. § 271.

13. Accordingly, if this Court deems the Paragraph IV Notification to be sufficient to trigger the deadline for Plaintiffs to sue Defendants under 21 U.S.C. § 355(j)(5)(B)(iii) and 21 C.F.R. § 314.107(b)(3), Plaintiffs seek all available relief under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*. and other applicable laws for Defendants' infringement of the '292 and '771 patents.

Jurisdiction & Venue

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

15. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

16. Upon information and belief, Endo is registered to do business in New York as a foreign corporation (No. 4832398) and Par is registered to do business in New York as a domestic corporation (No. 4965731). Upon information and belief, Defendants have a registered agent in the State of New York located at C T Corporation System, 111 Eighth Avenue, New York, New York 10011.

17. This Court has personal jurisdiction over Defendants, and venue is proper in this district, by virtue of the fact that, *inter alia*, they have committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C.

§ 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including in the State of New York. Defendants have indicated that they intend to engage in the commercial manufacture, use, or sale of the ANDA Product under the '314 ANDA before the expiration of the patents-in-suit, throughout the United States, including in the State of New York.

18. Upon information and belief, Endo is in the business of, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of New York, through its own actions, and through the actions of its agents and affiliates, including, at least, Par.

19. Upon information and belief, Par is in the business of, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of New York, through its own actions, and through the actions of its agents and affiliates.

20. Upon information and belief, Endo and/or Par hold a Pharmacy Wholesale License from the State of New York under License No. 027015 and Pharmacy Manufacturer Licenses from the State of New York under License Nos. 029055 and 101405.

21. Upon information and belief, Endo and Par have participated and collaborated in the preparation, filing, and seeking FDA approval of the '314 ANDA for the ANDA Product; continue to participate and collaborate in seeking FDA approval of the '314 ANDA; and intend to participate and collaborate in the commercial manufacture, marketing, offer for sale, and sale of the ANDA Product throughout the United States including the State of New York.

22. Defendants' infringing activities with respect to the filing of the '314 ANDA and intent to commercialize the ANDA Product have led and/or will lead to foreseeable harm and injury to Plaintiffs.

23. This Court also has personal jurisdiction over Defendants, and venue is proper in this district, by virtue of the fact that, upon information and belief, *inter alia*, Defendants have availed themselves of the rights and benefits of New York law, and have engaged in systematic and continuous contacts with the State of New York.

24. This Court also has personal jurisdiction over Defendants, and venue is proper in this district, because they have previously submitted to the jurisdiction of this Court and have further previously availed themselves of this Court consenting to this Court's jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Endo Pharms. Inc. v. Par Pharm. Cos., Inc.*, C.A. No. 12-9261-GBD (S.D.N.Y.) (Par and Endo, which was then named Par Pharmaceutical Companies, Inc., did not contest jurisdiction, and Par filed counterclaims); *Purdue Pharma L.P. v. Par Pharms., Inc.*, C.A. No. 13-3374-SHS (S.D.N.Y.) (Par filed counterclaims and did not contest jurisdiction); *Endo Pharms. Inc. v. Par Pharm. Cos., Inc.*, C.A. No. 13-3284-TPG (S.D.N.Y.) (Par filed counterclaims).

Insys's NDA, the Patents-In-Suit, and SYNDROS™

25. Insys holds New Drug Application ("NDA") No. 205525 on SYNDROS™ (dronabinol oral solution), 5 mg/mL, and is the exclusive distributor of SYNDROS™ in the United States.

26. On July 17, 2012, the '292 patent, entitled "Liquid Cannabinoid Formulations" was duly and legally issued to Insys Tx. A copy of the '292 patent is attached as Exhibit A.

27. Insys Dev currently owns the '292 patent.

28. On May 24, 2016, the '771 patent, entitled "Oral Cannabinoid Formulations" was duly and legally issued to Insys Dev. A copy of the '771 patent is attached as Exhibit B.

29. Insys Dev currently owns the '771 patent.

30. The patents-in-suit are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for SYNDROS™.

31. On July 31, 2017, Insys launched commercial availability of SYNDROS™, the first and only FDA-approved liquid dronabinol, for health care professionals to prescribe for use in treating (i) anorexia associated with weight loss in patients with AIDS and (ii) nausea and vomiting associated with chemotherapy in cancer patients who have failed to respond adequately to conventional antiemetic treatments.

Par's ANDA and Paragraph IV Notification

32. Upon information and belief, Par, with the collaboration or assistance of Endo, submitted the '314 ANDA to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), including a certification with respect to the patents-in-suit under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, seeking approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the ANDA Product prior to the expiration of the patents-in-suit.

33. Par sent Insys the Paragraph IV Notification, representing that Par has filed the '314 ANDA and a paragraph IV certification contained therein, with respect to the '292 and '771 patents. The Paragraph IV Notification further represents that Par is seeking approval of the ANDA Product prior to the expiration of those patents.

34. This action is being commenced by Plaintiffs within 45 days of the date of their receipt of the Paragraph IV Notification.

35. The Paragraph IV Notification was accompanied by an Offer of Confidential Access ("OCA") to certain confidential information regarding the ANDA Product. Insys

subsequently negotiated with Par in an effort to agree on reasonable terms for such confidential access. As of the time of filing of this Complaint, however, the parties have not able to reach an agreement with respect to reasonable revisions that Plaintiffs proposed to the OCA.

36. To date, Par has not provided Plaintiffs with a copy of any portions of the '314 ANDA or any information regarding the ANDA Product, beyond the information set forth in the Paragraph IV Notification.

Count I: Declaratory Judgment of Improper Paragraph IV Notification

37. Plaintiffs re-allege paragraphs 1–11 and 14–36 as if fully set forth herein.

38. By sending Insys a Paragraph IV Notification, Defendants represented that the related '314 ANDA is substantially complete and sufficient to serve as the basis for triggering the ANDA patent litigation process.

39. The '314 ANDA is statutorily required to contain "information to show that the [ANDA Product] is bioequivalent to the listed drug" (21 U.S.C. 355(j)(2)(A)(iv)) which is the previously approved product—i.e., SYNDROS™ (21 U.S.C. §§ 355(j)(2)(A)(i), 355(j)(7)(A)(i)).

40. While the Paragraph IV Notification is dated June 22, 2017, SYNDROS™ was not commercially available for bioequivalence testing until at least July 31, 2017. Consequently, the Paragraph IV Notification incorrectly suggests that the '314 ANDA is substantially complete and thus capable of serving as the basis of a paragraph IV certification.

41. An actual, substantial, and justiciable controversy exists between Plaintiffs and Defendants regarding whether the Paragraph IV Notification is therefore improper, null, void, and without legal effect, and whether Defendants improperly triggered the ANDA litigation process.

42. The controversy concerning the validity and effectiveness of the Paragraph IV Notification will cause Plaintiffs to suffer substantial prejudice and unnecessary legal fees and other costs unless the controversy and its surrounding uncertainty are resolved by this Court.

Count II: Par's Infringement of the Patents-In-Suit

43. Plaintiffs re-allege paragraphs 1–4 and 12–36 as if fully set forth herein.

44. By seeking approval of the '314 ANDA to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the ANDA Product prior to the expiration of the '292 and '771 patents, Defendants have infringed those patents under 35 U.S.C. § 271(e)(2)(A).

45. Defendants are jointly and severally liable for infringement of the '292 and '771 patents under 35 U.S.C. § 271(e)(2)(A). Upon information and belief, Defendants actively and knowingly caused to be submitted, assisted with, participated in, contributed to, or directed the submission of the '314 ANDA seeking to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the ANDA Product prior to the expiration of the patents-in-suit.

46. Moreover, if Defendants manufacture, use, offer for sale, or import into the United States any of the ANDA Product, or induce or contribute to any such conduct, prior to the expiration of the '292 and '771 patents, including any applicable exclusivities or extensions, they would infringe one or more claims of those patents-in-suit under 35 U.S.C. § 271(a), (b) and/or (c).

47. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the '314 ANDA be a date that is not

earlier than the expiration date of the patents-in-suit, or any later expiration of any patent term extension or exclusivity for the patents-in-suit to which Plaintiffs become entitled.

48. Plaintiffs will be irreparably harmed by Par's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Prayer for Relief

Plaintiffs request that the Court grant the following relief:

Declaratory Judgment of Improper Paragraph IV Notification

A. A declaratory judgment: (1) that Defendants' Paragraph IV Notification is improper, null, void, and without legal effect and that Defendants were not entitled to attempt to trigger the Hatch–Waxman patent litigation process; (2) that the Paragraph IV Notification did not commence the 45-day period in which to file a patent infringement action pursuant to 21 U.S.C. § 355(j)(5)B)(iii); and (3) that any 30-month stay of FDA approval of the '314 ANDA is either tolled or has not begun to run, as Plaintiffs have not received valid notice of paragraph IV certification with respect to the patents covering SYNDROS™.

B. An order preliminarily and permanently enjoining Defendants: (1) to withdraw the Paragraph IV Notification, which is improper, null, void, and without legal effect and (2) to refrain from sending to Plaintiffs notice of a paragraph IV certification until the FDA properly receives a substantially complete ANDA that includes the statutorily required showing of bioequivalence to the listed drug (i.e., SYNDROS™);

C. An award to Plaintiffs of their reasonable attorney's fees and costs in bringing this action; and

D. Such other and further relief as this Court may deem just and proper.

In the Alternative, a Finding of Infringement Under 35 U.S.C. § 271

E. If this Court deems Defendants' Paragraph IV Notification to be sufficient to trigger the deadline for Plaintiffs to sue Defendants under 21 U.S.C. § 355(j)(5)(B), an order adjudging and decreeing that Defendants have infringed the '292 and '771 patents by submitting the '314 ANDA to the FDA;

F. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the '314 ANDA will not be earlier than the expiration date of the '292 and '771 patents, or any later expiration of any patent term extension or exclusivity for the aforementioned patents-in-suit to which Plaintiffs are or become entitled;

G. An order permanently enjoining Defendants, their directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from manufacturing, using, offering to sell, selling, marketing, distributing, or importing the ANDA Product identified in this Complaint, or any product that infringes the '292 and '771 patents, prior to the expiration of the patents-in-suit, including any extensions to which Plaintiffs are or become entitled;

H. That Plaintiffs be awarded monetary relief to the extent Defendants commercially manufacture, use, offers for sale, or sell within the United States, or import into the United States any product that infringes or induces or contributes to the infringement of the '292 and '771 patents, within the United States prior to the expiration of the aforementioned patents, including any later expiration of any patent term extension or exclusivity for the patents to which Plaintiffs are or will become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest; and

I. Such other and further relief as this Court may deem just and proper.

PAUL HASTINGS LLP

/s/Gerald J. Flattmann, Jr.

Gerald J. Flattmann, Jr. (GF-4793)
Chad J. Peterman (CP-4526)
200 Park Avenue
New York, NY 10166
(212) 318-6000

Attorneys for Plaintiffs

OF COUNSEL:

Naveen Modi
Michael A. Stramiello, Ph.D.
PAUL HASTINGS LLP
875 15th St, NW
Washington, DC 20008
(202) 551-1700

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